

Claims 40, 41, 65, 66, 70-76, 79-95 and 112-114 are rejected under 35 U.S.C. §112, first paragraph. Applicants respectfully traverse the rejection.

In determining whether a claim meets the written description requirement, "the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed." MPEP §2163.02. The subject matter of the claims does not need to be literally described in the specification. Instead, it is only necessary that the description clearly conveys that Applicants invented what is being claimed. MPEP §2163.04.

The present claims are directed to methods in which only an area of human skin whose integrity has not been breached by injury or by a wound is contacted with the composition. As noted in the Office Action, this language is not specifically recited in the specification. However, the specification clearly conveys that Applicants invented the concept of applying the composition to human skin whose integrity has not been breached by injury or by a wound. In particular, the specification recites that the composition may be used for both cosmetic and medicinal purposes. Page 1, lines 6-7. As medicinal uses, the specification recites preservative treatment of skin grafts and disorders of cicatrization such as bedsores, varicose ulcers, stretch marks and keloids and/or a delay of cicatrization. Page 4, lines 17-27. These medicinal purposes clearly include applying the composition to areas of the skin whose integrity has been breached by injury and/or a wound. Thus, by reciting cosmetic applications as well as medicinal applications, the Applicants clearly envisioned the use of this product on skin whose integrity has not been breached by injury or a wound.

In addition, it is respectfully submitted that the specification describes uses in which the composition is applied only to areas of skin whose integrity has not been breached by injury or a wound. In particular, the specification describes using the composition for the

"maintenance of the integrity and the balance of the superficial cells of the skin." Page 3, lines 31-32 (emphasis added). This teaching is clearly directed to applying the composition to skin whose integrity has not been breached by injury or a wound.

Further, it is respectfully submitted that the phrases "weakened skin" and "older skin" discussed in the specification encompass skin whose integrity has not been breached by injury or a wound. In particular, the fact that skin is weakened, such as by age, does not mean that it is injured or wounded. As defined in a medical dictionary, PDR Medical Dictionary, the term "injury" refers to "[t]he damage or wound of trauma" (copy attached). Weakened skin provided by age would not be considered the damage of trauma. In addition, weakened skin is clearly not considered to be wounded. Therefore, it is respectfully submitted that these phrases provide further support for the invention as presently claimed.

In addition, use of the term "only" in the claims does not imply that treatment of nearby injured skin is avoided. Instead, it merely states that the treatment of injured or wounded skin is not within the claimed invention. By describing applications in which the composition is brought into contact with skin that has not been injured or wounded, as discussed above, the specification provides support for limiting the claims to those applications where the claimed composition is brought into contact only with skin whose integrity has not been breached by injury or a wound.

The specification as originally filed clearly conveys that Applicants invented the subject matter of the present claims. Therefore, the rejection of claims 40, 41, 65, 66, 70-76, 79-95 and 112-114 under 35 U.S.C. §112, first paragraph, should be reconsidered and withdrawn.

Claim 87 is rejected under 35 U.S.C. §112, second paragraph. Applicants respectfully traverse the rejection.

Claim 87 is directed to a method where the complex nutrient medium constitutes an excipient and the excipient potentiates an active principal. Claim 87 has been amended to clarify the invention. It is respectfully submitted that one of ordinary skill in the art would understand the claim as presently drafted. In particular, one of ordinary skill in the art is well aware of active principals that can be added to cosmetic compositions. In addition, one of ordinary skill in the art is well aware of how to use a complex nutrient medium of the present invention to potentiate such active principals.

Claim 87 clearly recites the invention. Therefore, the rejection of this claim under 35 U.S.C. §112, second paragraph, should be reconsidered and withdrawn.

Claims 40, 41, 65, 66, 70-76, 78-95 and 112-114 are rejected under 35 U.S.C. §103 over the combination of the Lindenbaum patents in view of the Wille patents and further in view of Cuca. Applicants respectfully traverse the rejection.

The claims are drawn to methods of cosmetic treatment where only skin "whose integrity has not been breached by injury" or "by a wound" is brought into contact with a particular composition. In the prior Amendment, Applicants used the term "blemished" to refer to skin that is not perfect. One of ordinary skill in the art is well aware that human skin is never perfect. Thus, "normal" skin is blemished. Factors, such as age, cause skin to become more "blemished," as the term is used herein. However, in the absence of an injury or a wound, it is respectfully submitted that applying the composition to such "blemished" skin would be within the claims. The point of the discussion of blemished skin in the previous Amendment was merely to indicate that the phraseology included in the claims was not intended to exclude skin that is not perfect, including skin that has become more blemished with age. Instead, the phraseology is intended to exclude only that skin whose integrity would be considered to be breached by injury or a wound.

The Lindenbaum patents do not teach or suggest methods in which only skin whose integrity has not been breached by injury or a wound is treated with the composition recited therein. In particular, the Lindenbaum patents are particularly directed to methods for treating wounds. Although the Lindenbaum patents teach that the composition includes a cell growth stimulating compound "in an amount effective for stimulating the growth of cells which surround, have been injured by or are responsible for healing a wound" and that "the function of the nutrient medium is to provide nutrients to normal, distressed and injured cells which surround or comprise the wound to be treated in order to enhance the growth and repair mechanism which are responsible for healing of the wound" (emphasis added), the Lindenbaum patents do not provide any motivation to apply the composition only on areas of the skin whose integrity has not been breached by injury or a wound. In particular, the motivation for providing nutrients to normal skin in the Lindenbaum patents is so that the surrounding areas can aid in healing of the wound. That is, Lindenbaum shows treating normal skin, only for healing purposes, by stimulating cellular growth, so that new epithelial cells will colonize at the injured skin. The Lindenbaum patents do not teach or suggest that the composition would provide beneficial properties that are unrelated to healing a wound. Therefore, there would have been no motivation to apply the compositions of the Lindenbaum patents only to skin whose integrity has not been breached by injury or a wound.

The secondary references do not overcome the deficiencies of the Lindenbaum patents. As discussed in the Office Action, the Wille patents teach other serum-free media useful for the culture of keratinocytes. However, for at least the reasons discussed in the Amendment filed July 22, 1999, Applicants respectfully submit that the Wille patents do not teach or suggest a process comprising contacting the composition with skin whose integrity has not been breached by injury or a wound. In addition, as discussed in the Office Action,

Cuca teaches delivery systems for topical preparations formulated as water-in-oil emulsions. However, Cuca does not teach or suggest using a composition within the recitations of the present claims in a cosmetic treatment comprising contacting only an area of human skin whose integrity has not been breached by injury or a wound with such a composition.

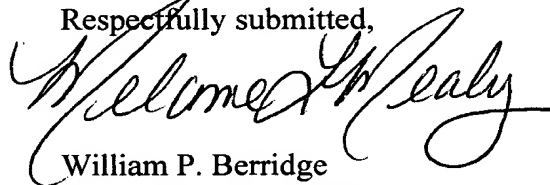
The cited references do not teach or suggest the present invention. Therefore, the rejection under 35 U.S.C. §103 should be reconsidered and withdrawn.

Claims 115-129 have been added to further define the invention. Claims 115-125 are patentable for at least the reasons discussed above. Claims 126 and 127 are directed to a method in which the composition is applied to skin weakened by a lack of nutrients and/or hydration. Claims 128 and 129 are directed to a method in which the composition does not comprise a cellular growth stimulating compound or factor. The applied references do not teach or suggest the features of claims 126-129.

In view of the above amendments and remarks, it is respectfully submitted that the above-identified patent application is in condition for allowance. Favorable consideration and prompt allowance are therefore respectfully requested.

Should the Examiner believe anything further would be necessary in order to place the application in better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below.

Respectfully submitted,



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Attachment:
Medical Dictionary Definition

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PDR MEDICAL DICTIONARY
FIRST EDITION

PDR[®]

*Medical
Dictionary*

MEDICAL ECONOMICS
MONTVALE, NEW JERSEY

in-jure (in'jer). To wound, hurt, or harm.

in-ju-ry (in'jer-ē). The damage or wound of trauma. [L. *injuria*, fr. *in-* neg. + *jus* (*jur-*), right]

blast i., tearing of lung tissue or rupture of abdominal viscera without external i., as by the force of an explosion.

closed head i., a head i. in which continuity of the scalp and mucous membranes is maintained.

contrecoup i. of brain, an i. occurring beneath the skull opposite to the area of impact.

coup i. of brain, an i. occurring directly beneath the skull at the area of impact.

current of i., SEE *current of injury*.

degloving i., avulsion of the skin of the hand (or foot) in which the part is skeletonized by removal of most or all of the skin and subcutaneous tissue.

egg-white i., SYN *egg-white syndrome*.

hyperextension-hyperflexion i., violence to the body causing the unsupported head to hyperextend and hyperflex the neck rapidly; does not imply any specific resultant trauma or pathology.

i. of intervertebral disk, SEE *traumatic cervical discopathy*.

open head i., a head i. in which there is a loss of continuity of scalp or mucous membranes; the term is sometimes used to indicate a communication between the exterior and the intracranial cavity. SEE ALSO *penetrating wound*.

pneumatic tire i., separation of the skin and subcutaneous tissue from the underlying fascia, classically occurring when an extremity is crushed and rolled over by the tire of a vehicle but may be incurred through other mechanisms that produce shear forces; may occur particularly in cases of obesity.

reperfusion i., myocardial impairment, usually with arrhythmia, following the opening of arterial blockage and considered to be due to oxygen-derived free radicals.

steering wheel i., trauma to the anterior chest wall caused by impact with the steering wheel during an automobile accident; can include fractured sternum and ribs, cardiac contusion, tear of the aorta or other great vessels, as well as lung injuries.

whiplash i., popular term for hyperextension-hyperflexion i.

in-lay (in'lā). 1. In dentistry, a prefabricated restoration sealed in the cavity with cement. 2. A graft of bone into a bone cavity. 3. A graft of skin into a wound cavity for epithelialization. 4. In orthopaedics, an orthomechanical device inserted into a shoe; commonly called an "arch support."

epithelial i., SYN *inlay graft*.

gold i., a gold restoration fabricated by casting in a mold made from a wax pattern; the restoration is sealed in the prepared cavity with dental cement.

porcelain i., a fused porcelain restoration luted in a cavity prepared in a tooth.

in-let. A passage leading into a cavity. SYN *aditus* [NA].

i. of larynx, the aperture between the pharynx and larynx, bounded by the superior edges of the epiglottis (anteriorly), the aryepiglottic folds (laterally), and the mucosa between the arytenoids (posteriorly). SYN *aditus laryngis* [NA], *laryngeal aperture*.

pelvic i., SYN *superior pelvic aperture*.

in-nate (i'nāt, i-nāt'). SYN *inborn*. [L. *in-nascor*, pp. -natus, to be born in, pp. as adj. *inborn*, *innate*]

in-ner-va-tion (in'er-vā'shūn). The supply of nerve fibers functionally connected with a part. [L. *in*, in, + *nervus*, nerve]

reciprocal i., contraction in a muscle is accompanied by a loss of tone or by relaxation in the antagonistic muscle. SYN *reciprocal inhibition* (1).

in-nid-i-a-tion (i-nid-ē-ā'shūn). The growth and multiplication of abnormal cells in another location to which they have been transported by means of lymph or the blood stream, or both. SEE ALSO *metastasis*. SYN *colonization* (1), *indenzation*. [L. *in*, in, + *nidus*, nest]

in-no-cent (in'ō-sent). 1. Not apparently harmful. 2. Free from moral wrong. [L. *innocens* (-ent-), fr. *in*, neg., + *noceo*, to injure]

in-noc-u-ous (i-nok'yū-ūs). Harmless. SYN *innocuous*. [L. *innocuus*]

in-nom-i-na-tal (i-nom'i-nā-tāl). Relating to the hip bone.

in-nom-i-nate (i-nom'i-nāt). SYN *anonyma*. [L. *innominatus*, fr. *in-* neg. + *nomen* (*nomin-*), name]

in-nox-i-ous (i-nok'shūs). SYN *innocuous*. [L. *in-noxius*, fr. *in-* neg. + *noceo*, to injure]

Ino Symbol for inosine.

ino-, **in-**. Obsolete prefix for fiber, fibrous; replaced in most terms by *fibro-*. [G. *is* (*in-*), fiber]

in-oc-u-l-a-bil-i-ty (i-nok'yū-lā-bil'i-tē). The quality of being inoculable.

in-oc-u-l-a-ble (i-nok'yū-lā-bl). 1. Transmissible by inoculation. 2. Susceptible to a disease transmissible by inoculation.

in-oc-u-late (i-nok'yū-lāt). 1. To introduce the agent of a disease or other antigenic material into the subcutaneous tissue or a blood vessel, or through an abraded or absorbing surface for preventive, curative, or experimental purposes. 2. To implant microorganisms or infectious material into or upon culture media. 3. To communicate a disease by transferring its virus. [L. *inoculo*, pp. -atus, to ingraft]

in-oc-u-la-tion (i-nok'yū-lā'shūn). Introduction into the body of the causative organism of a disease.

stress i., in clinical psychology, an approach intended to provide patients with cognitive and attitudinal skills that they can use to cope with stress.

in-oc-u-lum (i-nok'yū-lūm). The microorganism or other material introduced by inoculation.

In-o-cy-be (i-nō'si-bē). A genus of mushrooms containing several species that have a high yield of muscarine.

in-o-pec-tic (in-ō-pek'tik). Relating to inopia.

in-op-er-a-ble (in-op'er-ā-bl). Denoting that which cannot be operated upon, or cannot be corrected or removed by an operation.

in-o-pex-ia (in-ō-peksē-ā). A tendency toward spontaneous coagulation of the blood. [ino + G. *pexis*, fixation, + -ia]

in-or-gan-ic (in-ōr-gan'ik). 1. Not organic; not formed by living organisms. 2. SEE *inorganic compound*. 3. Not containing carbon.

in-os-a-mine (in-ōs'ā-mēn). An inositol in which an -OH group is replaced by an -NH₂ group.

in-os-co-py (in-ōs'kō-pē). The microscopic examination of biologic materials (e.g., tissue, sputum, clotted blood) after dissecting or chemically digesting the fibrillary elements and strands of fibrin. [ino- + G. *skopeō*, to look at]

in-ose (in'ōs). SYN *inositol*.

in-o-se-mia (in-ō-sē-mē-ā). 1. The presence of inositol in the circulating blood. 2. SYN *fibremia*. [inos + G. *haima*, blood]

in-o-si-nate (in-ō'si-nāt). A salt or ester of inosinic acid.

in-o-sine (I, Ino) (in'ō-sēn). 9-β-D-Ribosylhypoxanthine: a nucleoside formed by the deamination of adenosine. SYN *hypoxanthosine*.

in-o-sine 5'-di-phos-phate (IDP). Inosine esterified at its 5' position with diphosphoric acid.

in-o-sine 5'-mon-o-phos-phate (IMP). SYN *inosinic acid*.

IMP dehydrogenase, an enzyme that catalyzes the reaction of IMP, water, and NAD⁺ to form NADH and xanthosine 5'-monophosphate (XMP), the immediate precursor of GMP.

in-o-sine pran-o-bex (in'ō-sēn pran'ō-beks). A 1:3 molar complex of 1-dimethylaminopropan-2-ol-4-acetamidobenzoate and inosine, used as an antiviral agent.

in-o-sine 5'-tri-phos-phate (ITP) (in'ō-sēn). Inosine with triphosphoric acid esterified at its 5' position; participates in a number of enzyme-catalyzed reactions.

in-o-sin-ic acid (in-ō-sin'ik). A mononucleotide found in muscle and other tissues; a key intermediate in purine biosynthesis; also produced in relatively high levels in muscle. SYN *inosine 5'-monophosphate*.

in-o-sin-i-case (in-o-sin'-a-kās). An enzyme that functions in purine biosynthesis and catalyzes the ring closure reaction that produces inosinic acid from 5'-phosphoribosyl 5-formamidoimidazole-4-carboxamide.

in-o-sin-yl (in-ō'si-nil). The radical of inosinic acid.